Importing FDA Regulated Items

Information Regarding Arthrex's Imports and the United States Government's FDA Regulations

Arthrex®

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Imports, U.S. Customs and the Food and Drug Administration

All imports into the U.S. require a customs declaration at the time of arrival into the United States. U.S. Customs and Border Protection (CBP) reviews documentation and physically inspects items to determine if the goods will be allowed entry for commercial distribution, also known as free circulation. All declaration information is transmitted to CBP via an electronic Automated Broker Interface (ABI). The ABI system transmits CBP entry and other information to the appropriate agencies simultaneously. The following list identifies documents required for a U.S. Customs import/entry as described in 19 CFR 141.86 – 141.89:

- Commercial Invoice – must include the following information for all products:
  - A description of the product in English
  - The U.S. Harmonized Tariff Schedule (HTS) Number
  - The country of origin
  - Product quantity and value
- Packing List
- Air waybill or Bill of Lading
- Certificate of origin – if necessary for Free Trade Agreement confirmation.
- Any additional documentation requested by CBP or another Agency

After reviewing the documentation, CBP and the Agency will respond electronically with their release or detention information. Each regulatory agency will issue their separate determination regarding the item's admissibility into the U.S. After all agencies release the product from their custody, import and distribution of the item may occur.

What is an Arthrex Import?

If Arthrex purchases an item from a foreign supplier, or purchases an item from a U.S. supplier that sources the item internationally, the item is subject to U.S. Customs and Border Protection (CBP) inspection, control and admissibility determination. Customs has enforcement agreements with over 40 Federal agencies, called 'Participating Government Agencies' agreements; Customs enforces its own regulations and works closely with each Agency to enforce all applicable regulations. The U.S. Food and Drug Administration (FDA) and Customs have signed an Agency agreement authorizing Customs to assist FDA with enforcing its import regulations.
Chapter 19 of the Code of Federal Regulations, (the Customs regulations, or 19 CFR), governs the import of goods into the USA, and Chapter 21 of the Code of Federal Regulations, (the FDA regulations, or 21 CFR), governs the import, manufacture, sale and use of foods, cosmetics, drugs and medical devices.

The Customs Modernization Act of 1993 requires U.S. Importers of record meet a reasonable care standard when importing goods. Arthrex is responsible for using reasonable care when determining the tariff classification, value, origin and any other information CBP requires to import product into the U.S., including fulfilling FDA or other Agency import requirements.

Does Arthrex Import Items Subject to Other Government Agency Regulations?

Government agencies regulate the majority of Arthrex products. As the Importer of Record, Arthrex must determine which Agency regulates the imported item and submit the necessary information with the Agency via the ABI System.

Currently, Arthrex imports the following items and this list is not exclusive:

- Finished Medical Devices
- Medical Device Components
- Medical Device Instruments
- Medical Device Parts
- Computer related machines and parts – Synergy machines, parts and software.

The U.S. FDA regulates medical devices and the FDA and the Federal Communications Commission (FCC) regulate Computer/Electronic devices. Each agency has its own requirements that Arthrex must fulfill to import computer / electronic devices into the U.S. Two additional FDA agencies regulate medical devices.

Center for Devices and Radiological Health (CDRH) - Responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products.

Center for Biologics Evaluation and Research (CBER) - Regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER ensures biological products are safe and effective.

What FDA Requirements must Arthrex Fulfill?

To fulfill FDA requirements, Arthrex's domestic and foreign suppliers and contract manufacturers **must register annually** with FDA. FDA provides a list of all parties required to register their establishments for FDA authorization to import medical devices for distribution within the U.S.

Manufacturers that register with FDA must also list their devices with FDA. FDA will issue a medical device listing number for a group of similar products made by the manufacturer. Arthrex, as an importer, **must report** the listing information to FDA at the time of import.

In addition to Manufacturer registration information, Arthrex must also report the FDA product code and Affirmation of Compliance (AOC) codes for FDA clearance purposes. The FDA product code is an alphanumeric descriptor for the imported item, based upon the commodity determination of the product. For example, FDA's product code for Arthrex's medical device instrumentation is 87L—XH. FDA provides an online product code builder to help importers determine the correct product code classification.

FDA requires importers report the Affirmation of Compliance (AOC) code for all imports of medical devices, whether or not they are finished devices. The AOC is a descriptive data element that identifies specific information FDA requires to determine clearance, release from custody and entry of an imported item. FDA provides an online list of all AOC codes to help importers determine the correct AOC to report.

Who is Required to Register with FDA and What is Arthrex Required to Report?

FDA requires the following parties register; corresponding definitions and AOC reporting requirements as defined by the FDA regulations within 21 CFR Part 820.3:

Initial Importer

- The party that takes first possession of the product or the Importer of Record.
- DII – Device Initial Importer Registration number. Arthrex Inc.'s DII number is 1220246

Manufacturer

- 20 CFR 820.3(o) … "any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions."
- Makes a device that meets the definition of a device as defined by FDA 20 CFR 820.3(l)
- DEV – Device Manufacturer Registration number, for example: 3007123456
- Owner/Operator number – FDA provides this number to the manufacturer during the registration process. FDA will allow an importer to report this number in place of the registration number during the interim period of application and issuance of the final registration number, for example: 10012345

Foreign Manufacturer

- The Foreign manufacturer of the product as defined above.
- DEV – Device Foreign Manufacturer Registration number Example: 3007123456
- Owner/Operator number – FDA provides this number to the manufacturer during the registration process. FDA will allow an importer to report this number in place of the registration number during the interim period of application and issuance of the final registration number, for example: 10012345

Contract Manufacturer

- "Manufactures a finished device to another establishment's specification."
- DEV – Device Foreign Manufacturer Registration number Example: 3007123456
- Owner/Operator number – FDA provides this number to the manufacturer during the registration process. FDA will allow an importer to report this number in place of the registration number during the interim period of application and issuance of the final registration number, for example: 10012345

Component Manufacturer

- Manufactures a component part of a finished device that will be sent to a finished device manufacturer for further processing and finishing.
- CPT – Device Component – used when importing a component of a device that requires further processing or will be included in a finished device after import.
- Not required to register for FDA purposes. However, FDA requires importers report AOC information.

Who is Required to Register with FDA and What is Arthrex Required to Report?

Pre-Market Notification Number (510k)

- This AOC and qualifier should be the Device Pre-Market Notification number or 510(k) number issued by FDA/CDRH. The foreign manufacturer has the primary responsibility to obtain and report this number; however, this can be delegated to the initial importer or distributor. A manufacturer must submit a pre-market notification when introducing a new device to the market and any modifications of a current device that significantly affect its safety and effectiveness. The PMN number should always be the number that is on the listing record.
- PMN – Device Premarket Notification Number (510k) – The qualifier for this code should be the device premarket notification (510k) number issued by CDRH for the product identified on the FDA line. The qualifier will begin with the letter "K", for example: PMN K123456

Investigational Device Exemption Number

- This AOC and qualifier should be the Investigational Device Exemption number issued by FDA/CDRH. Devices that qualified experts use on human subjects, to conduct investigations of their safety and effectiveness, are considered investigational devices.
- IDE – Investigational Device Exemption Number – The qualifier for this code should be the Investigational device exemption number issued by FDA/CDRH for the product identified on the FDA line. The qualifier will begin with the letter "G", for example: IDE G012345

The FDA's website contains more information on these topics.

What are Medical Device Reporting Requirements?

There are many types of medical devices, and depending upon the classification of the devices different registration and reporting requirements. Medical devices fall within three Classes:

Class I – General Controls
- With exemptions
- Without exemptions – premarketing submission required

Class II – General and Special Controls – Require reporting of:
PMN – "Device (CDRH) Premarket Notification Number (510k)
- Qualifier example: PMN K979009
- With exemptions
- Without exemptions – premarketing submission required

Class III – General Controls and Premarket Approval –Require reporting of:
PMA – "Device (CDRH) Premarket Approval Number
- Qualifier example: PMA P975555

The FDA's regulations, 21 CFR 820.3, define and describe reporting requirements:
- Medical Device – Federal Food, Drug, and Cosmetic Act (FD&C Act) 21 U.S.C 321 § 201(h):
  - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
- All Medical Devices require reporting Affirmation of Compliance (AOC) information:
  - DII – Device Initial Importer Registration number (Registration number for Importer). Arthrex Inc.'s DII number is 1220246
  - DEV – Device Manufacturer Registration number Example: 3007109793
  - LST – Device Listing Number – an AOC qualifier for the identification of the registered device, for example, LST E199100
- Some devices identified below have different reporting requirements, instead of or in addition to, the general reporting requirements identified above.

What are Medical Device Reporting Requirements?

■ Finished Device 21 CFR 820.3(l):

- "... any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized."
- PMN – "Device (CDRH) Premarket Notification Number (510k)
  - Qualifier example: PMN K979009

■ Instruments – General exempt - Class I

- PMN – Not required

■ Component 21 CFR 820.3(c):

- "... any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device."
- CPT – Device Component – Declared when importing a component of a device that requires further processing or will be included in a finished device after import.
- No qualifier necessary.
- LST – Not Required
- PMN – Not Required.

More FDA Information

U.S. Food and Drug Administration
Medical Device Regulations Overview
Who Must Register, List and Pay the Fee
Establishment Registration & Device Listing database
Is The Product A Medical Device?
FDA Definitions
Frequently Asked Questions about Device Registration and Listing Requirements

Please communicate with Global Trade Operations, (GTO@Arthrex.com), if you have questions about these topics.

Letter to Suppliers

Dear Supplier,

In 2012, the United States Food and Drug Administration (US FDA) amended its Medical Device User Fee regulations. The Amendments require the following establishments to annually register, pay their user fees and list any medical devices they produce:

- Manufacturers including Contract Manufacturers, and Remanufacturers
- Sterilizers
- Kit Assemblers
- Contract Packagers, and
- Specification Developers

All contract manufactures of “finished devices” must register and list devices they produce, regardless of commercial distribution of the product. USFDA defines finished medical devices as
“Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.”

FDA further defined components and accessories as
“Any raw material, substance, piece, part, software, labeling, or assembly which is intended to be included as part of a finished, packaged, and labeled device” provided to a finished device manufacturer.

A component or accessory is also a “finished medical device” if it is packaged or labeled for commercial distribution to an end user.

As an Arthrex supplier, you or your source are required to register and list all products manufactured to Arthrex specifications. US FDA requires all importers, including Arthrex, to report the following information for medical device imports:

- Actual/contract manufacturer - name and address
- The FDA product code for the item
- The manufacturer’s FDA registration number – DEV
- The product device listing number associated with the manufacturer – LST
- 510k number if applicable – PMN

As an Arthrex supplier, you must provide the above-required information on your commercial invoices and shipment summaries to enable Arthrex to import your domestic or foreign products. This information is mandatory.

Please speak with your Arthrex Supply Chain Buyer if you have questions regarding these requirements.

You may also go to the US FDA’s website, www.FDA.gov, for more information about US FDA import requirements.

Best Regards,

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